EasyMax Voice III

Self-Monitoring Blood Glucose System

User's Manual

Please read this User's Manual thoroughly before using your blood glucose meter.

Dear EasyMax Voice III SMBG System Owner,

Thank you for using the **EasyMax Voice III** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be dependable, easy-to-use, compact, lightweight and portable to help you monitor your blood glucose on a regular basis.

Please read this manual thoroughly before you begin testing. This manual provides you and your diabetes care team with important information and step-by-step direction to use the **EasyMax Voice III** Self-Monitoring Blood Glucose System.

Thanks again for choosing the **EasyMax Voice III** SMBG System.

Intended Use

The **EasyMax Voice III** Self Monitoring Blood Glucose Test System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. In addition, this device is not intended for the diagnosis of or screening for diabetes and not intended to be used in visually impaired users and neonates.

Standard Accessories

Your new **EasyMax Voice III** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- Blood Glucose Meter
- 10 Test Strips
- Carrying Case
- 2 Alkaline Batteries
- 10 Lancets
- Lancing Device

- AST Lancing Device Cap
- User's Manual
- Quick Reference Guide
- Log Book
- Normal Control Solution
- Control Solution Instructions

Optional Accessories

- Low Control Solution
- High Control Solution



- 1. Normal control solution is included with the system.
- 2. Low control solution and High control solution are available. For purchase, please contact your local dealer.

Why is it so important to test blood glucose regularly?

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We've made this SMBG system as simple as possible to help you to use the meter regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

Do you need Help?

If you have questions or need assistance, please contact your healthcare professional. You can also visit www.epsbio.com for diabetes management tools and product demonstrations.



Although the EasyMax Voice III SMBG System is easy to use, you may need to consult your healthcare professional (this may be your doctor, pharmacist or diabetes nurse educator) for instructions on how to use the system. Only the correct use of the system will ensure accurate results.

Important Information About Your New Meter

- EasyMax Voice III blood glucose meter is designed and approved for testing fresh capillary blood from fingertip, palm or forearm. The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- Only use EasyMax Voice III blood glucose meter with EasyMax Voice III Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimen.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect reading. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car, a bathroom or a refrigerator.
- Keep the meter, test strips and lancing device away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Elevated levels of acetaminophen, uric acid, gentisic acid, L-Dopa, dopamine, ascorbic acid (vitamin C) and methyldopa may affect the test results.
- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.

- Remove batteries if the meter will not be used for one month or more.
- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.
- Consult with your healthcare professional before testing on your forearm.



- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 3048 meters above sea level has no effect on readings.

Health-Related Information

- If you are very dehydrated, urinating frequently, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your doctor right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, or if you have questions, please talk to your doctor.
- Please read your test strip instructions carefully for additional health-related information.



Warning for potential biohazard:

Healthcare professionals using this system on multiple patients should handle all products or objects in contact with human blood carefully to avoid transmitting viral disease, even after cleaning.

Explanation of Symbols

$\bigcap_{\mathbf{i}}$	Consult instructions for use	\triangle	Caution
LOT	Batch code	(2)	Do not reuse
IVD	In vitro diagnostic medical device	LR3/AAA + DC 3V 2XAAA	1.5V(AAA) x 2 batteries only
Σ	Use by	1	Temperature limitation
	Manufacturer	REF	Catalogue number
SN	Serial number	CONTROL	Control
Σ	Sufficient for	EC REP	Authorised representative in the European Community
ϵ	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices		



88-88	Date	Ú	Before Meal (AC)
88:88	Time	(After Meal (PC)
888	Result	×	Mute
888	Record/Average display	◄ '))	Volume
[5	Control Solution		Insert strip
En	English		Temperature
E5	Espańol	×	Error
A	АМ		Upload data
P	PM	M	Memory
54	24hr	•	Apply Blood
	Battery	mg/dL mmol/L	Unit



When ③) shows up in any sections of use's manual, the meter sounds and tells you the instructions.

Description of Sound

WHEN the meter will speak	WHAT the meter will say
Turn on the meter.	Turn-on music and greeting songs.
Start to set the meter.	Please run the setting. English (En) / Español (ES).
To set the volume.	Please set the volume.
To set the year	Please set the year.
To set the date.	Please set the date.
To set the time.	Please set the time.
Meter is ready to Insert test strips.	Please insert a test strip.
Before applying blood to the meter.	Please flag the test. Before meal, please confirm. After meal, please confirm. Control solution, please confirm.
When the meter is ready to apply blood.	Please apply blood into the strip.
Blood Glucose test is completed and the result is shown on screen.	Blood glucose is (number) milligram per deciliter.
Humidified / Used strips.	Humidified or used strips. Please replace with a new strip.
Low Power.	Low power. Please replace with new batteries.
System error.	System error. Please replace the batteries.

WHEN the meter will speak	WHAT the meter will say	
Blood Glucose test result is ABOVE the measurement range of 35.0 mmol/L (630 mg/dL).	Unable to measure. Test result is higher than 630 milligram per deciliter. Please test again and if you get the same result, please contact your healthcare professional immediately.	
Blood Glucose test result is BELOW the measurement range of 1.1 mmol/L (20 mg/dL).	Unable to measure. Test result is lower than 20 milligram per deciliter. Please test again and if you get the same result, please contact your healthcare professional immediately.	
Press C button to delete a memory.	Please confirm the deletion.	
Memory was deleted.	Memory deleted.	
Memory mode.	(7/14/30/60/90) day average is (number) milligram per deciliter.	
If the blood is not enough.	Insufficient blood. Please try with a new strip.	
Temperature is too high and it may affect the test results.	Temperature is too high.	
Temperature is too low and it may affect the test results.	Temperature is too low.	
Turn off the meter.	Goodbye and turn-off music.	



There is no speaking function for "Viewing & Deleting Test Results" in the Chapter 4.

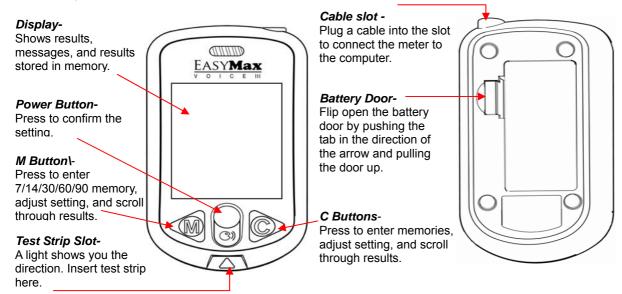
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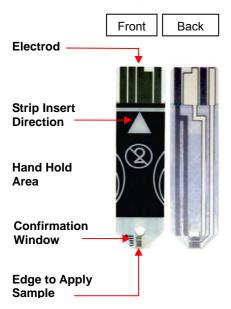
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Chapter 1: Understanding Your Meter

The EasyMax Voice III Blood Glucose Meter



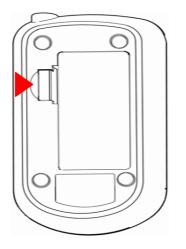
The EasyMax Voice III Accessories Blood Glucose Test Strip

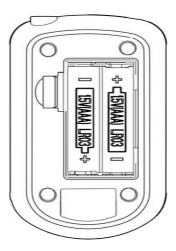


Test Strip Bottle



Installing Batteries





- **1.** Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.
- 2. Insert two batteries. You will hear opening music.
- **3.** Put the battery door back in place and snap it closed.

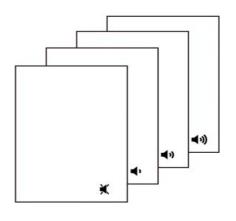
Setting the Language and Volume—First Time Use



 Insert new batteries, the meter turns on. Press M button to select En or press C button to select ES. (En= English, ES = Español)



2. And press power button to confirm the setting.



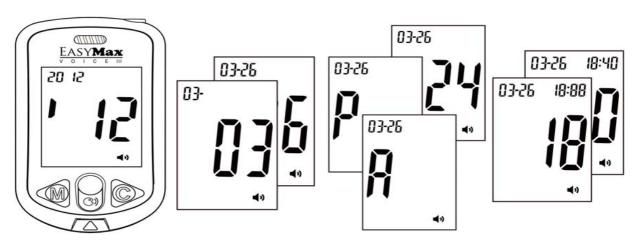
3. Repeat step 1 and 2 to set the volume.



- 1. The priority language of the blood glucose meter is set in English.
- 2. The unit of blood glucose meter is set at mg/dL or mmol/L. If the display shows the wrong unit, please contact your local dealer for repair.

Setting the Time and Date—First Time Use

Setting the current time and date in your meter is important if you intend to use the meter memory.



- Press M button and C button to set the year. Press power button to confirm the setting.
- **2.** Repeat step 1 to set the date.
- Repeat step 1 to select P, A or 24 mode and then set the time. (P=PM, A=AM, 24=24hr mode.)

Using EasyMax Voice III Blood Glucose Test Strip

- Use only with **EasyMax Voice III** Blood Glucose Meter.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original bottle.
- Close the bottle tightly right away, after you take a test strip out. This keeps the test strip dry.
- Use the test strip within three minutes after you take it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the "Expiration date" on the test strip bottle. The test strip is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 2°C 30°C (35.6°F 86°F). Do not freeze.
- Do not apply blood or control solution to the test strip until you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.

Chapter 2: Control Solution Testing

Why Run A Control Solution Test

We recommend that you run the **EasyMax Voice III** Normal control test because it lets you know that your meter and test strips are working properly to give you reliable results. You should run the control solution test when:

- You use the **EasyMax Voice III** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.



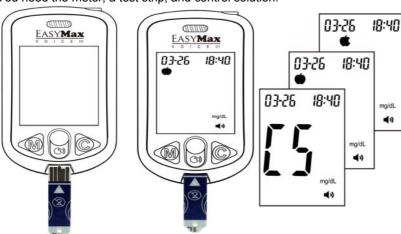
Professional users are instructed to follow federal, state, and local guidelines.

About The Control Solution

- Use only with **EasyMax Voice III** test strips.
- Write the date you opened the bottle on the bottle label. The control solution is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- The control solution can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store the bottle of control solution at room temperature, between 2°C- 30°C (35.6°F 86°F). Do not freeze.

Running A Control Solution Test

You need the meter, a test strip, and control solution.



 Put a test strip into the meter in the direction of the arrow. 2. The meter turns on.

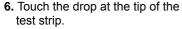
Press M button or C button to select CS, press power button to confirm the control solution mode.

mans before meal mode and means after meal.)



- **3.** Place the meter on a flat surface, like a table.
- **4**. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.
- Squeeze the bottle until a tiny drop forms at the tip of the bottle.



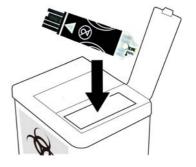


7. The meter starts to count down from 5 seconds and then shows the result.



8. Do not remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.

Press power button to repeat the test result. Or you can also press C button or M button to set the volume before repeating the result.



10. Remove the test strip and throw it away after you have compared the reading to the range printed on the test strip bottle.



Understanding Control Solution Test Results

The label on your test strip bottle shows the acceptable ranges for the Control Solutions. The result you get should be inside this range. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:



Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.

Troubleshooting Checks

- Was the test strip exposed to open air for a long period of time?
- ✓ Was the test strip bottle capped tightly?
- ✓ Was the meter functioning well?
- ✓ Is the control solution expired or contaminated?
- Were test strips and control solutions stored in cool, dry places?
- ✓ Did you follow the testing steps properly?

Action

If yes. Repeat the control test with properly stored strips.

If the bottle was not capped tightly, the strips could be humidified. Replace the test strips.

If not. You can use control solution to verify the meter's functions. (Chapter 2)

If yes. Replace with new control solution to check the performance of SMBG system.

If not. Repeat the control test with properly stored strips or control solutions.

Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to obtain the inaccurate results, please contact your local dealer.

Chapter 3: Testing Your Blood Glucose

Using The Lancing Device

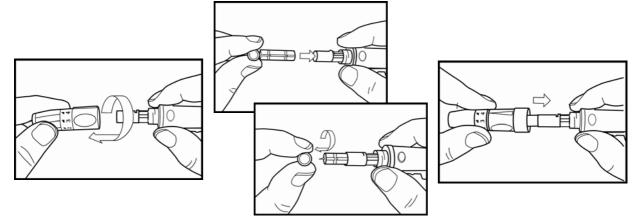
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.



Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. The users may discuss methods for disposing of used test strips and lancets with their doctor.

Inserting A Lancet Into The Lancing Device

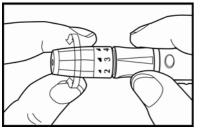
You must first load the lancet into the lancing device to get it ready for use.

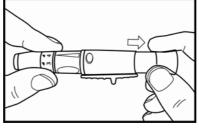


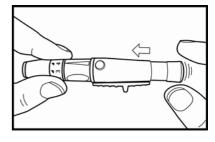
1. Unscrew the Cap.

2. Insert the lancet into the lancing device firmly then twist off the protective cover.

3. Recap the front cap.







Select the desired penetration depth.

5. Pull on the sliding barrel of the lancing device until it clicks and then release.

Now the lancing device is ready. Do not prick your finger until your meter and strip are prepared.

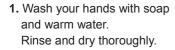
6. Set the lancing device aside until later in the test



Select 1-2 for soft or thin skin, 3 for average, and 4-5 for thick or calloused skin.

Running A Blood Glucose Test With Blood From Your Fingertip



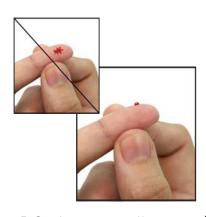


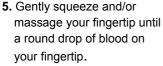


- 2. Put a test strip into the meter in the direction of the arrow. The meter turns on. Press M button or C button to select AC/PC mode and press power button to confirm the setting.
- 3. When the blood drop flashes on the display, the meter will tell the instruction.



4. Using the lancing device. Hold the lancing device firmly against the side of your finger. Press the trigger button. Then remove the lancing device from your finger. 29







- 6. Touch the blood drop at the tip of the transparent window of the test strip. Do not put blood on top of the strip. Be sure to get enough blood in the strip's confirmation window. Otherwise, an inaccurate reading may result.
- The meter starts to count down from 5 seconds and speaks the result.



- 8. Press power button to repeat the test result. Or you can also press C button or M button to set the volume before repeating the result.
- **9.** Remove the test strip and the meter turns off automatically.



- 1. Please make sure to apply blood when the blood drop appears on the display.
- 2. Please check if the result on the display is the same as audible result.

Alternate Site Testing (AST)

Understanding Alternate Site Testing

What is AST?

Besides the fingertip, you can test the forearm.

What is the advantage of AST?

You have the option of testing other places on your body besides the fingertip.

Consult your health care professional before you begin using the forearm for testing. AST that should be used with this device is the forearm only. Blood glucose test results obtained from your forearm may differ significantly from fingertip samples.

We strongly recommend that you:

Do AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do NOT use AST if:

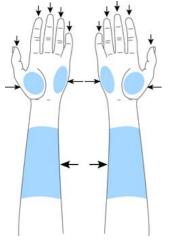
- You think your blood glucose is low.
- You often do not notice when your blood glucose is low.
- Your AST results do not match the way you feel.
- You think your blood glucose is high.
- Your routine glucose results are often fluctuating.

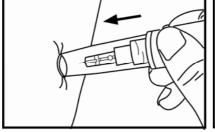
Fingertip test only:

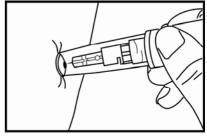
- If sick
- If blood glucose is low
- After exercising
- Two hours or less after eating
- After injecting rapid-acting insulin (two hours or less)
- When you have just taken insulin
- If the blood glucose test result does not match how you feel, do a fingertip test to confirm the result again.
- If you often do not notice when your blood glucose is low, do a fingertip test.

Running A Blood Glucose Test With Blood From Your Palm and Forearm

Please use the clear cap with the lancing device for AST testing.

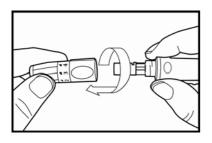


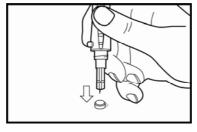


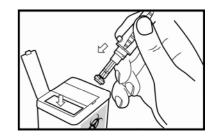


- Massage the puncture area of palm or forearm for a few seconds
- 2. Press and hold the device with clear adjustable tip against the forearm.
- Press the trigger button to activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

Discarding Used Lancets







1. Unscrew and remove the cap.

2. Without touching the used lancet, stick the lancet tip into its protective cover.

3. Pointing the lancing device toward a container for sharp or biohazard material, slide the ejection button down to release the covered lancet into the container.

Understanding Your Test Results

The **EasyMax Voice III** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult without diabetes is 3.88~6.11 mmol/L (70~110 mg/dL). Two hours after meals, the blood glucose range for an adult without diabetes is less than 6.66 mmol/L (120 mg/dL). For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.

Unusual Test Results

If your test result doesn't match the way you feel, please follow these steps:

- Run a control solution test, Chapter 2 "Control Solution Testing."
- 2. Repeat a blood glucose test, Chapter 3 "Testing Your Blood glucose."
- 3. If your test results still don't reflect the way you feel, call your doctor immediately.



- 1. Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.
- 2. A red blood cell count (Hematocrit) that is either very high (above 55%) or very low (below 30%) may not provide accurate results. If you do not know your hematocrit level, please consult your healthcare professional.
- 3. Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.

Symptoms Of High Or Low Blood Glucose

Being aware of the symptoms of high or low blood glucose can help you understand your test results and decide what to do if they seem unusual. Here are the most common symptoms:

Greater than 13.33 mmol/L (240 mg/dL)

What It Means:

The test result is higher than reference normal range. (3.89~6.11mmol/L or 70~110mg/dL)

Symptoms:

Fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

What to Do:

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is greater than 13.33 mmol/L (240 mg/dL) and you have symptoms of high blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Below 3.33 mmol/L (60 mg/dL)

What It Means:

The test result is lower than reference normal range. (3.89~6.11mmol/L or 70~110mg/dL)

Symptoms:

Sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

What to Do:

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is below 3.33 mmol/L (60 mg/dL) and you have symptoms of low blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Comparing Your Meter Result To A Lab Result

A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to the doctor's office for a blood glucose test. The results will probably not match, even if you are fasting. This is typically not a problem with your meter, it just means that time has elapsed and your blood glucose has changed.

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than **EasyMax Voice III** blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

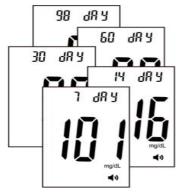
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.



- 1. Do not change your therapy based on one individual result in memory.
- 2. The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting the time and date" in Chapter 1.
- Once 480 results are in memory, adding a new result causes the oldest one to be deleted.
- 4. Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.

Viewing & Deleting Test Results

The meter provides 7, 14, 30, 60 and 90 days averaging to help track your blood glucose trend soundlessly.



- **1.** Press power button to turn on the meter.
- Press M button to view averages for 7/14/30/60/90



Press C button to view individual test result.



- 4. To delete a test result, press C button for more than 3 seconds and display shows "dEL". Then press power button to confirm the deletion.
- **5.** Press C button to keep reviewing the results.
- **6.** Press M button to go back to averages for 7/14/30/60/90 days.



- Press power button for 1 seconds and the meter will repeat the test results.
- 2. Press power button for 3 seconds to turn off the meter or the meter turns off automatically in 90 seconds.

Meter Setup

Using The Set Mode

By using the set mode, you can personalize your meter to suit your needs. Here are the features you can customize —

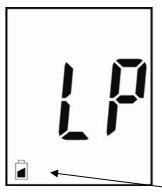
Time and Date — to set the time and date (see Chapter 1).

Language — to set the language (see Chapter 1).

Volume – to set the volume (see Chapter 1)

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries are also acceptable, but the capacity of test times may differ. Install the batteries when you first use the meter or replace with new batteries when the "LP" (low power) message and the low battery symbol appear on the display.

The meter will not turn on the first time batteries are installed.

Please press and hold power button or insert the test strip to turn your meter on. The meter will turn off automatically. Or you can press and hold power button to turn your meter off.

Low battery symbol



- 1. The meter won't delete earlier records after you replace batteries.
- 2. You should reset the time and date again after you replace the batteries.
- 3. 1.5V (AAA) x 2 batteries are available at most stores. You may take the old batteries with you for replacement.
- 4. Remove batteries when you will not be using the meter for one month or more.

Cleaning Your Meter

Caring for your **EasyMax Voice III** SMBG system does not require special cleaning. Please keep the meter free of dirt, dust, bloodstain, and water stains. Follow these guidelines carefully to help you get the best performance possible:

Do:

- Make sure the meter is turned off.
- Gently wipe the meter's surface with a soft cloth slightly dampened with ethanol (70~75%).

Do Not:

- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

Maintenance And Testing



Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

To make sure the display is working properly, turn off the meter. Press and hold power button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please contact your local dealer.

Cleaning Your Lancing Device

- To clean the lancing device, wipe with a soft cloth dampened with water and mild detergent.

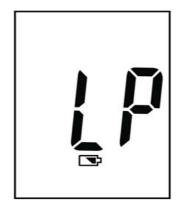
 DO NOT place the entire device under water.
- To disinfect the cap after cleaning. Place it in 70%-75% rubbing alcohol for 10 minutes at least once a week. Allow the cap to air-dry after disinfecting.

Screen Messages And Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, please contact your local dealer.

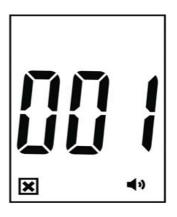


Humidified/Used strips *Action:* Replace with a new strip.



Low power

Action: Replace with new batteries.

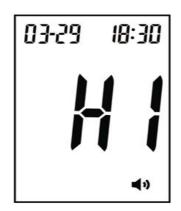


System fault

Action: Replace the batteries first.

If ERROR 001 appears again,
please contact your local dealer.







Memory fault

Action: Replace the batteries first. If Err appears again, please contact your local dealer.

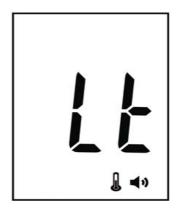
Test result is higher than 35.0 mmol/L (630 mg/dL) Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please contact your healthcare professional.

The test result is lower than 1.1 mmol/L (20 mg/dL)

Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please contact your healthcare professional.



The "Ht" and thermometer icon appears. Temperature is too high, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues. *Action:* Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).



The "Lt" and thermometer icon appears. Temperature is too low, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues. *Action:* Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).

Chapter 6: Technical Information

Specifications

Brand name		EasyMax Voice III Blood Glucose Meter	
Range		1.1~35.0 mmol/L (20~630 mg/dL)	
Test time		5 seconds	
Memory sets		480 test results	
Operating condition	Temp.	10°C - 40°C (50°F - 104°F)	
	Relative Humidity	R.H. ≤ 90%	
Plood sample		0.6 μL	
Blood sample		Fresh blood from fingertip, palm or forearm	
Hematocrit (Hct)		30-55%	
Power		2 Alkaline 1.5V (AAA)	
Battery life		Over 2000 tests	
Display dimension		46.0 × 33.0 mm	
Device dimension H × W × D (mm)		92.2 x 49.7 x 23 mm	
Weight		44.6 grams w/o batteries	
Principles		Electrochemical biosensor technology	

Limitation

The test strips are used for fresh capillary whole blood samples.

- 1. DO NOT use neonate blood sample.
- 2. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
- 3. The system should be used at a temperature between 10°C 40°C (50°F 104°F). Outside this range, the system may get incorrect results.
- 4. DO NOT reuse the test strips. The test strips are for single use only.
- 5. Red blood cell count (Hematocrit); Hematocrit levels between 30% and 55% will not significantly affect the results, Hematocrit levels below 30% may cause higher results, Hematocrit levels above 55% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
- 6. Altitude up to 3048 meters above sea level has no effect on readings.

Healthcare Professionals – Please note these additional Limitations

- 7. Patients undergoing oxygen therapy may have inaccurate results.
- 8. If the patient has the following conditions, the result may fail:
 - Severe dehydration
 - ♦ Severe hypotension (low blood pressure)
 - Shock
 - ◆ A state of hypoglycemic-hyperosmolar state (with or without ketosis)
- Lipemic samples: Cholesterol level up to 500 mg/dL and triglycerides up to 3,000 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with EasyMax Voice III Glucose Meter.

- 10. Critically ill patients should not be tested with home-use blood glucose meters.
- 11. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Bias Glucose Level Concentrations of the interferant tested	50 mg/dL	250 mg/dL	500 mg/dL
Ascorbic Acid,3 mg/dL	9.5	6.0%	1.0%
lbuprofen,40 mg/dL	-2.0	-1.8%	-1.7%
L-Dopa,10 mg/dL	85.1	30.5%	1.1%
Sodium Salicylate,50 mg/dL	1.8	-0.6%	-0.1%
Tetracycline,0.4 mg/dL	0.4	2.1%	-0.6%
Tolbutamide,100 mg/dL	0.8	-1.5%	1.0%
Bilirubin-unconjugated,1.2 mg/dL	-0.2	-3.7%	-5.5%
Uric acid,14 mg/dL	26.8	5.6%	9.3%
Xylose,20 mg/dL	1.4	4.2%	5.5%

Device Information

EasyMax Voice III SMBG System,

EasyMax Voice III Blood Glucose Test Strips,

EasyMax Voice III Blood Glucose Meter,

EasyMax Voice III Normal Control Solution,

EasyMax Voice III Low Control Solution,

EasyMax Voice III High Control Solution.



Reference:

* American Diabetes Association: Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p.S37



Manufacturer:

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E-mail: mail@obelis.net

Warranty

EPS warrants the original purchaser for a period of 3 years from the date of purchase. This means during the warranty period if your Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.

Lancing Device & Lancet

Meets the requirements of MDD 93/42/EEC



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